

REMARKS

Claims 21, 26, 27, and 29-31 remain rejected under 35 USC 103(a) as being unpatentable over WO 94/28902 in view of Sui et al (US 6,077,841). Claims 25, 28, 32 and 33 remain rejected under 35 USC 103(a) as being unpatentable over WO 94/28902 in view of Sui et al (US 6,077,841) and further in view of Purewal et al (US 5,225,183).

Applicant's respectfully disagree with the Examiner's assertion that "it would have been obvious to one of ordinary skill in the art to combine the two references and conclude that any compound of the class PDE V inhibitors can be made in an inhalation form because of its convenience of use and fast onset of action as well as reduced side effect profile." As clearly set forth in the MPEP (2143.01), "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." In this instance, there is no motivation provided in either reference that would guide one of ordinary skill in the art to choose inhalation as a mode of administration, over any other mode of administration, for the specific compounds of claim 21 in a method of treating sexual dysfunction. WO 94/28902 teaches orally administering sildenafil. With regard to Sui et al, there is no guidance, suggestion or teaching, other than the fact that inhalation is listed in the disclosure of Sui et al, along with tablets, pills, capsules, powders, granules, parenteral solutions, suspensions, metered aerosol or liquid sprays, drops, ampoules, auto-injector devices, or suppositories, to choose inhalation as the mode of administration. In fact, the only specific embodiment that is given is an oral composition. See example 4. The essence of the teaching of Sui et al is that in order to overcome the shortcomings of Sildenafil, one of skill in the art should look to new compounds, not to different modes of administration for Sildenafil.

With regard to Purewal, the examiner states that applicants are attacking references individually and that "one of ordinary skill would be motivated to look for a suitable propellant when working on preparing an aerosol formulation." It is noted that the teaching of each individual reference must be assessed in order to determine whether they can be combined, and if so, what the combined teaching would be. In the instant case, there is nothing in WO 94/28902, Sui or Purewal that would motivate one of ordinary skill to administer the claimed compounds in an inhalable form to treat ED. WO 94/28902 teaches orally administering Sildenafil. Sui suggests investigating alternative PDE V inhibitors, preferably for oral administration, or at least by not favoring inhalation over any other

route. Purewal teaches 1,1,1,2-tetrafluoroethane is a useful green alternative to CFCs in aerosol formulations that contain a variety of medicaments, but does not mention any PDE V inhibitors.

In view of the foregoing, it is respectfully submitted that the claims of the instant invention are patentable over WO 94/28902 in view of Sui et al (US 6,077,841) and further in view of Purewal (US 5,225,183) and allowance of the claims is earnestly solicited.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080
(862) 778-7809

D. Gabrielle Brouillette

D. Gabrielle Brouillette
Agent for Applicant
Reg. No. 51,384

Date: December 01, 2003